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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,095	06/30/2003	Wies Ter Laak	2001-1196-1	8141

466 7590 07/27/2005

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EXAMINER	
LEITH, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,095	TER LAAK ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *10-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.o 21

DETAILED ACTION

Claims 1-28 are pending in the application.

The Affidavit submitted on 4/15/05 by Inventor van der Beek was fully considered and will be discussed *infra.*

This application contains claims 10-22 drawn to an invention nonelected with traverse in the response filed 8/3/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-9 and 23-28 were examined on their merits.

Claim Rejections - 35 USC э 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 9 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stack (US 5,221,745) in view of Suzuki et al. (US 5,543,415) and further in view of Meier et al. (2000) for the reasons of record.

Applicant's arguments, as well as the Affidavit filed by the Inventor were fully considered, but not found persuasive.

Applicant's principal argument presides in the contention that because Meier et al. taught that V. agnus-castus may be used in the treatment of premenstrual syndrome, that they are not all used for the same purpose (p.8, Arguments). However, it is clear from Stack that dopamine D2 receptor agonists are effective for treating depression, even though Meier et al. was silent on this intrinsic property of rotundifuran. The ordinary artisan would have had a reasonable expectation that because rotundifuran was a dopamine D2 receptor agonist, and because dopamine D2 receptor agonists were known in the art for the beneficial treatment of depression, that rotundifuran would have been at least somewhat effective in treating rotundifuran.

Applicant argues that "the declaration provides unexpected evidence of the advantageous effects of the combination of cocoa and a plant derived dopamine D2 receptor agonist (p. 8, Arguments). However, it is noted that the declaration only provides data with regard to a specific *Cimicifuga racemosa* extract containing 2.5% triterpene glycosides and an unknown cocoa extract (the Examiner refers to this cocoa

extract as 'unknown' because it is not known what type of extract it is). Therefore, the data presented in the Affidavit does not bear a reasonable correlation to what is actually claimed. Further, if the data presented in the Affidavit did bear a reasonable correlation to what is actually claimed, it is not found where the data presents any unexpected results. It is found that the cocoa extract and the particular C. racemosa extract have an additive effect, however, this is not considered an unexpected result. Further, again, the data does not correlate to the claimed invention and therefore is not sufficient evidence to conclude that the invention, as claimed, would have had any unexpected results over what was already known in the art – that each element was known for treating depression and therefore the combination of each element would have provided for an additive effect.

Applicant argues that "STACK simply fails to suggest that cocoa can be advantageously combined with a dopamine D2 receptor agonist" (p. 10, Arguments). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that "the main cocoa xanthines (i.e. caffeine and theobromine) have hydrogen on the R4 position of formula (I) as depicted by SUZUKI et al. in column 2. Thus, SUZUKI et al. relate to different molecule and does not relate to cocoa

xanthines or cocoa powder" (p. 11, Arguments). However, it is deemed that a substitution of a simple hydrogen molecule is obvious practice in the prior art, especially when synthetically manufacturing a product. The ordinary artisan would have had a reasonable expectation that xanthine, the naturally occurring compound, would have had similar depression-ailing properties as synthetic xanthines as disclosed by Suzuki et al.

Applicant argues that "MEIER et al. do not relate to the problems associated with the administration of cocoa, nor does MEIER et al. give nay hint towards the advantageous combination of cocoa and a dopamine D2 receptor agonist" (p. 11, Arguments). Applicant further argues that none of the references teach all of the claimed elements (pp. 11-12, Arguments). However, again, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues "as none of the publications teach that the combination and proportions are result-effective variables, applicants believe that one of ordinary skill in the art would lack the motivation to optimize the parameters as suggested by the Office action (p. 13, Arguments). However, it is noted that in each reference is found suggestions and/or obvious modifications of the claimed invention. Since dopamine D2

receptor agonists were known to be effective in treating depression, and because rotundifuran was a dopamine D2 agonist, the ordinary artisan would have had a reasonable expectation that rotundifuran would have treated depression. Because xanthine analogs were known for treating depression, the ordinary artisan would have had a reasonable expectation that xanthine, the naturally occurring compound in cocoa, would have also treated depression because xanthine is the core structure of xanthine analogs, and further, that some of the structures proposed by Suzuki et al. were obvious variants of xanthine. Absent any unexpected results, it is deemed that the combination of the elements would have been clear to the ordinary artisan with the references before him.

Claims 1-8 and 23-25 remain rejected and new claims 26-28 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (US 5,543,415) in view of Foster et al. (1999).

New claims 26-28 are drawn specifically to a cocoa or cocoa extract and *C. racemosa* or *C. racemosa* extract. It is noted that this particular combination of elements was made obvious in the previous Office Action in regard to Suzuki et al. in view of Foster et al.

Applicant's arguments, as well as the Affidavit filed by the Inventor were fully considered, but not found convincing.

Applicant argues that "FOSTER et al. discuss the treatment of 'depressive moods'....'depressive moods' are specifically linked to premenopausal and menopausal symptoms and are not related to clinical depression" (pp. 13 - 14, Arguments). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims do not state 'clinical depression'; rather, the claims simply state 'depression'. It is well known, and disclosed by Foster et al. that depression is linked to premenstrual syndrome. Foster et al. specifically administer *Cimicifuga racemosa* for treating depression caused by premenstrual disorder, and thus, the teachings of Foster et al. are deemed to make obvious a the method for treating depression as indicated by the claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

07/20/05